

Junshi Biosciences Announces FDA's Approval of IND Application for Phase 2/3 Clinical Study of JS207 for the Neoadjuvant Treatment of NSCLC Patients

SHANGHAI, China, October 16, 2025 -- Shanghai Junshi Biosciences Co., Ltd (Junshi Biosciences, HKEX: 1877; SSE: 688180), a leading innovation-driven biopharmaceutical company dedicated to the discovery, development, and commercialization of novel therapies, announced that the investigational new drug ("IND") application for an open-label, two-arm, randomized, active-controlled, phase 2/3 clinical study comparing the company's product, recombinant humanized anti-PD-1/VEGF bispecific antibody (code: JS207), to nivolumab for the neoadjuvant treatment of patients with stage II/III, resectable, actionable genomic aberration (AGA)-negative, non-small cell lung cancer ("NSCLC") has been approved by the U.S. Food and Drug Administration (the "FDA").

Lung cancer is currently a malignant tumor with the highest prevalence and mortality rate in the world. According to GLOBOCAN, there were approximately 2.48 million new lung cancer cases and approximately 1.82 million lung cancer deaths worldwide in 2022. NSCLC is a major subtype of lung cancer, accounting for approximately 85% of all cases. Amongst these cases, 20%-25% are surgically resectable at first diagnosis, but even after radical surgical treatment, 30%-55% of these patients suffer from post-surgical recurrence and death. Currently, immune checkpoint inhibitors, represented by anti-PD-1 monoclonal antibodies combined with chemotherapy, have been widely used in the perioperative treatment of resectable NSCLC, and show significant improvements in event-free survival (EFS), pathological complete response (pCR), and overall survival (OS). However, patients with resectable NSCLC still face low survival and cure rates, among other unmet clinical needs.

The study is an open-label, two-arm, randomized, active-controlled, international multi-center phase 2/3 clinical study comparing the efficacy and safety of JS207 to nivolumab for the neoadjuvant treatment of patients with stage II/III, resectable, AGA-negative NSCLC. JS207 is now the first PD-1/VEGF dual-target drug approved for conducting confirmatory study in patients eligible for surgery. Professor Yilong WU from Guangdong Provincial People's Hospital will be the principal investigator.

Dr. Jianjun ZOU, General Manager and CEO of Junshi Biosciences, said, "As a high-potential candidate in Junshi Biosciences' next-generation immuno-oncology portfolio (I-O 2.0), JS207 has undergone a series of proof-of-concept (POC) studies targeting prevalent cancers in China and globally. In this ongoing Phase 2/3 clinical trial evaluating neoadjuvant therapy for resectable lung cancer, we have chosen to directly challenge first-generation PD-1 monoclonal antibodies with JS207. By harnessing cutting-edge innovative therapies, we aim to offer more patients better treatments and a better future. The international regulatory authorities have recognized our clinical demand-driven R&D plus scientifically rigorous study design, and their validation is highly encouraging. Moving forward, we will accelerate our global development efforts to make JS207 a cornerstone of the I-O 2.0 portfolio and achieve evolutionary breakthroughs in immuno-oncology."

About JS207

JS207, a recombinant humanized anti-PD-1/VEGF bispecific antibody, was independently developed by Junshi Biosciences for the treatment of advanced malignant tumors. Currently, JS207 has been approved for conducting phase 2/3 clinical study, and multiple ongoing phase 2 clinical studies are exploring it in combination with chemotherapy, monoclonal antibodies, antibody-drug conjugates (ADCs) and other drugs in NSCLC, colorectal cancer, triple-negative breast cancer, liver cancer and other tumor types.

JS207 can simultaneously bind to PD-1 and VEGFA with high affinity, effectively blocking the binding of PD-1 to PD-L1 and PD-L2 while also inhibiting the binding of VEGF to its receptor. JS207 has the efficacy of both immunotherapeutic drugs and anti-angiogenic drugs. Through the neutralization of VEGF, JS207 inhibits the proliferation of vascular endothelial cells, improves the tumor microenvironment, and increases the infiltration of cytotoxic T lymphocytes in the tumor microenvironment, thereby achieving better anti-neoplasm activity.

JS207's design is based on the high-affinity, clinically proven and differentiated anti-PD-1 drug, toripalimab as the backbone. The anti-PD-1 moiety of JS207 adopts a Fab structure to maintain binding affinity to PD-1, thereby attaining better enrichment in the tumor microenvironment. The anti-VEGF moiety has a binding affinity for human vascular endothelial growth factor that is comparable to that of bevacizumab. In non-clinical in vitro cytological tests, compared with the combination of an anti-PD-1/PD-L1 monoclonal antibody and a VEGF monoclonal antibody, a bispecific antibody simultaneously targeting PD-1/PD-L1 and VEGF demonstrated significantly enhanced PD-1 antigen binding and internalization, as well as synergistic enhancement of the NFAT signaling pathway, thereby better activating immune cells in the tumor microenvironment.

About Junshi Biosciences

Founded in December 2012, Junshi Biosciences (HKEX: 1877; SSE: 688180) is an innovation-driven biopharmaceutical company dedicated to the discovery, development and commercialization of innovative therapeutics. The company has established a diversified R&D pipeline comprising over 50 drug candidates, with five therapeutic focus areas covering cancer, autoimmune, metabolic, neurological, and infectious diseases. Five of the company's products have received approvals in China and international markets, one of which is toripalimab, China's first domestically produced and independently developed anti-PD-1 monoclonal antibody. Toripalimab has been approved in over 40 countries and regions including China, the US, and Europe. During the COVID-19 pandemic, Junshi Biosciences actively shouldered the social responsibilities of a Chinese pharmaceutical company through its involvement in developing etesevimab, MINDEWEI®, and other novel therapies for the prevention and treatment of COVID-19.

With a mission of "providing patients with world-class, trustworthy, affordable, and innovative drugs," Junshi Biosciences is "In China, For Global." At present, the company boasts approximately 2,500 employees in the United States (Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc.). For more information, please visit: <http://www.junshipharma.com>.

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